Use of a Point of Care HIV Rapid-Rapid Testing Algorithm for Partners/Contacts in a Ryan White Clinic Can Facilitate Linkage to Care

Rogers, AL[1]; Mangine, CM[2]; Houser, KM[1]; Sarwari, AR[1]
[1] West Virginia University Positive Health Clinic, Morgantown, WV
[2] West Virginia University, School of Public Health, Department of Epidemiology

BACKGROUND

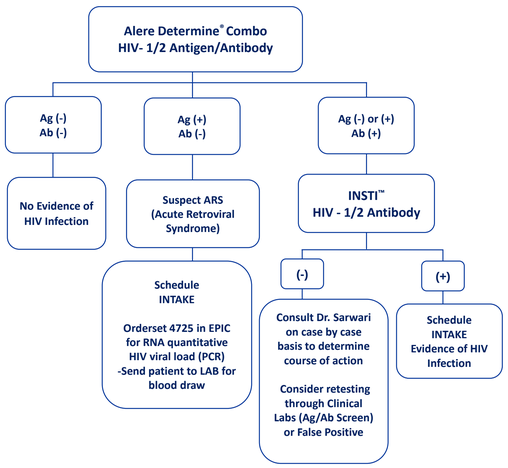
The practice of off-site confirmatory testing for HIV diagnosis can add additional barriers to medical care for patients by placing a lengthy time period between diagnosis and linkage to care.[1-2] According to the CDC, the greatest impact on viral suppression is at the point of diagnosis and linkage to care.[3] The CDC currently recommends an HIV algorithm beginning with a combination HIV-1/2 Ag/Ab test followed by an HIV differentiation assay.[4]

DESCRIPTION

In 2006, the Positive Health Clinic (PHC) established an HIV testing program offering free, rapid testing to the contacts of current patients. Contacts were encouraged to accompany the patient to a scheduled appointment in order to receive free testing.

A modified rapid HIV testing algorithm was established for these high risk individuals. Testing was performed using two CLIA waived rapid HIV tests: Alere Determine ® (4th generation) HIV 1/2 Ag/Ab Combo and INSTI™ HIV-1/2 Ab. The primary test utilized the 4th generation assay with reflex testing using a 2nd generation test for Ab only or Ag/Ab reactive specimens and RNA testing for Ag only reactive specimens. Persons with positive results received immediate counseling and scheduled intake to HIV care.

ALGORITHM



DEVELOPING THE ALGORITHM

Comparison – 50 Fingerstick Whole Blood Samples			
Rapid Test System	Ag (+)	Ag (-) / Ab (-)	Ag (-) / Ab (+)
Alere Determine® HIV-1/2 Antigen/Antibody Combo	0	37 / 37	13 / 13
INSTI™ HIV-1/2 Antibody		/ 37	/ 13
Oraquick Advance® HIV-1/2 Antibody		/ 37	/ 13

Three CLIA waived rapid HIV tests were compared for laboratory test validation purposes. Comparison testing was performed simultaneously in the following order for all 50 patients:

Determine, INSTI, Oraquick. Positive antibody results were confirmed with Abbott Architect Ag/Ab Screen / Multispot confirmation

Of the 13 positive samples, 7 were known positives (in care), and 6 were new positives (4 presented in case study results). If samples were negative using all three test kits and the patient had no known risk factors in the previous 3 weeks, no further testing was done.

Due to high sensitivity and specificity of the Alere Determine Combo, there is no reason to believe that positive infections went undetected.[5] Additionally, testing was performed one-on-one with individuals trained to determine risk for infection, specifically acute infections.

RESULTS FROM 4 CASE STUDIES

Case Study	(+) Rapid Tests	Number of Days to Intake	cART started	Follow up Date	Viral Load <200 at Follow-up Visit	Time to viral suppression (<200copies/mL^3) In days
1	06/25/2015	5	08/05/2015	09/02/2015	yes	69
2	06/25/2015	5	08/19/2015	09/23/2015	yes	90
3	07/22/2015	15*	08/11/2015	09/08/2015	yes	48
4	09/16/2015	6	10/21/2015	11/11/2015	yes	56
*Originally scheduled in 6 days (pt. cancelled)						

DISCUSSION

The standard of care practice in West Virginia for confirmatory HIV diagnosis involves several steps:

- Blood drawn
- Blood sample mailed and processed by the State Health Laboratory
- Results mailed back to the testing site
- Test administrators notify patients that results have been received
- Patients schedule in person appointment to receive results
- Schedule visit for HIV care provider
- INTAKE Labs drawn
- Start cART
- Achieve viral suppression

HIV positive patients receiving the standard of care practice for diagnosis can experience lengthy time periods between initial blood draw and linkage to care. Depending on the circumstance, this can take up to several months.

The National HIV/AIDS Strategy is to increase the proportion of all newly diagnosed HIV-positive patients successfully linked to HIV medical care within 90 days of diagnosis.[6] Anecdotally, PHC patients receiving the rapid HIV testing algorithm demonstrate an average of ~8 days to intake and ~66 days to documented viral suppression. Compared to the national goal using the modified algorithm for high risk individuals, patients from each case study exceed the national goal.

CONCLUSION

Offering free on site rapid testing to contacts of current patients at an established clinic could aid in reaching the national goal of linking patients to care within 90 days of diagnosis. Additionally, it provides an atmosphere for high risk individuals to seek testing who may not seek testing otherwise. Receiving point of care diagnosis in an established clinic may break down barriers and expedite linkage to care. This is particularly relevant in West Virginia and similar states experiencing additional barriers such as rurality.[7-8] Research is warranted.

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